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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KAZUNARI YAMAGUCHI, YOICHIRO HORII,
YOUICHI TAKAHAMA, and SHINYA NAGAI

Appeal 2010-000516
Application 10/805,220
Technology Center 1600

Before CAROL A. SPIEGEL, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is a decision on appeal[2] under 35 U.S.C. § 134 from the Examiner's rejection of claims 17, 24, and 26.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.
[2] Heard November 2, 2010.

We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claim 17 is representative of the claims on appeal, and reads as follows:

17. A method for determining whether a subject has been infected with Borna disease virus (BDV), comprising:

(a) providing a support having immobilized thereon p10 BDV synthetic antigen polypeptide and p24 BDV synthetic antigen polypeptide;

(b) reacting the resulting support with a sample from a living body; and

(c) assaying for both anti-BDV IgM antibody and anti-BDV IgG antibody which bind to said p10 BDV synthetic antigen polypeptide and said p24 BDV synthetic antigen polypeptide immobilized on said support, so as to detect said anti-BDV IgM antibody and/or anti-BDV IgG antibody in said sample, wherein said subject is determined to have been infected with BDV when said anti-BDV IgM antibody or said anti-BDV IgG antibody, or both said anti-BDV IgM antibody and said anti-BDV IgG antibody is detected,

wherein the p10 BDV synthetic antigen polypeptide has an amino acid sequence as set forth in SEQ ID NO: 8,

wherein the p24 BDV synthetic antigen polypeptide has an amino acid sequence as set forth in SEQ ID NO: 1.

Claims 24 and 27 are also drawn to methods of determining whether a subject has been infected with Borna disease virus. In claim 24, the synthetic antigens are a p10 BDV synthetic antigen polypeptide having an amino acid sequence as set forth in SEQ ID NO: 8; and a p40 BDV synthetic antigen polypeptide having an amino acid sequence as set forth in SEQ ID NO: 3. Claim 26 uses the synthetic antigens of SEQ ID NO: 8; SEQ ID NO: 1; and SEQ ID NO: 3.

The following ground of rejection is before us for review:

Claims 17, 24, and 26 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Yamaguchi,[3] Watanabe[4] as evidenced by Planz,[5] Hatalski,[6] and Carbone.[7] (Ans. 3.)

We reverse.

ISSUE

Has the Examiner established by a preponderance of the evidence that it would have been obvious to include a p10 BDV synthetic polypeptide consisting of an amino acid sequence of SEQ ID NO: 8 in the assay method taught by Yamaguchi?

FINDINGS OF FACT

FF1 Each of the independent assay claims on appeal requires a p10 BDV synthetic polypeptide having an amino acid sequence of SEQ ID NO: 8.

FF2 As taught by the Specification, SEQ ID NO: 8 consists of residues 43-57 of p10. (Spec. 15.)

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[3] Yamaguchi et al., *Synthetic peptide-based electrochemiluminescene immunoassay for anti-Borna disease virus p40 and p24 antibodies in rat and horse serum*, 38 ANNALS CLIN. BIOCHEM. 348-355 (2001).

[4] Watanabe et al., *Antibodies to Borna Disease Virus in Infected Adult Rats: An Early Appearance of Anti-p10 Antibody and Recognition of Novel Virus-Specific Proteins in Infected Animal Brain Cells*, 62 J VET. MED. SCI. 775-778 (2000).

[5] Planz et al., *Pathogenesis of Borna Disease Virus: Granulocyte Fractions of Psychiatric Patients Harbor Infectious Virus in the Absence of Antiviral Antibodies*, 73 J VIROL. 6251-6256 (1999).

[6] Hatalski et al., *Neutralizing Antibodies in Borna Disease Virus-Infected Rats*, 69 J VIROL. 741-747 (1995).

[7] Kathryn M. Carbone, *Borna Disease Virus and Human Disease*, 14 CLIN. MICROBIO. REV. 513-527 (2001).

FF3 The Examiner's statement of the rejection may be found at pages 3-5 of the Answer.

FF4 Specifically, the Examiner relies on Yamaguchi as teaching "a synthetic peptide-based electrochemiluminescence immunoassay (ECLIA) for anti-BDV p40 and p24 IgG antibodies in rat and horse serum." (Ans. 3.)

FF5 The Examiner finds that "Yamaguchi is silent on the use of the antigen polypeptide of p10 (SEQ ID NO: 8)." (*Id.* at 4.)

FF6 The Examiner cites Watanabe for its "study on the time course for appearance to antibodies to BDV antigens p40, p24, p18 and p10," wherein it was found that "anti-p10 antibodies (IgG) were detected in sera of BDV-infected rats as early as anti-p40 and anti-p24 antibodies." (*Id.*)

FF7 The Examiner further finds that "[n]either Yamaguchi nor Watanabe disclose Appellant's SEQ ID NO: 8." (*Id.*)

FF8 The Examiner finds, however, that as evidenced by Planz, the "sequence of p10 includes Appellant's SEQ ID NO: 8." (*Id.* at 5.)

PRINCIPLES OF LAW

While the analysis under 35 U.S.C. § 103 allows flexibility in determining whether a claimed invention would have been obvious, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), it still requires showing that "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* "Often, it will be necessary . . . to look to interrelated teachings of multiple [references] . . .

and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed[.]" *Id.* "[T]his analysis should be made explicit," and it "can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* "We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

ANALYSIS

Appellants argue that the references cited by the Examiner fail to teach or suggest the use of a p10 BDV synthetic polypeptide having an amino acid sequence of SEQ ID NO: 8. (App. Br. 10-12.) According to Appellants, "[t]here is no suggestion to combine Yamaguchi *et al.*'s assay to include detection of synthetic peptide p10 corresponding to SEQ ID NO:8 except from using Appellant's invention as a template through a hindsight reconstruction of Appellant's claims." (*Id.* at 14.)

We agree with Appellants. While the Examiner has established that the sequence of p10 is known and includes the sequence of SEQ ID NO: 8, the Examiner has not provided evidence or scientific reasoning as to why the ordinary artisan would have chosen residues 43-57 of p10 as the synthetic

antigen to be used in the assay of Yamaguchi. We are thus compelled to reverse the rejection.

CONCLUSION OF LAW

We conclude that the Examiner has not established by a preponderance of the evidence that it would have been obvious to include a p10 BDV synthetic polypeptide consisting of an amino acid sequence of SEQ ID NO: 8 in the assay method taught by Yamaguchi. We thus reverse the rejection of claims 17, 24, and 26 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Yamaguchi, Watanabe as evidenced by Planz, Hatalski, and Carbone.

REVERSED

cdc

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037